II. REMARKS

Before the amendments made herein, claims 97 to 101 and 119 to 127 were pending. Claims 119 to 122 have been canceled herein without prejudice, and claim 128 added. Accordingly, after the amendments made herein are entered, claims 97 to 101 and 123 to 128 will be pending.

A. Regarding the amendments

Claim 97, 123 and 125 have been amended herein to more clearly indicate that the recited preparation is pure enough to elicit anti-heparanase antibodies. The amendment is supported in the specification, for example, at page 43, lines 12-21; page 65, lines 11-15; and page 66, lines 8-17.

Finally, new claims 128 and 129 are directed to the variant of SEQ ID NO:10, which is disclosed in the specification, for example, in Figure 1 and at page 44, lines 14-20.

Because all of the amendments made herein are fully supported by the specification, no issue of new matter arises.

B. Regarding written description

Claims 119 to 122 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. Applicants respectfully traverse the rejection.

To promote prosecution of the subject application, Applicants have canceled claims 119 to 122 without prejudice. Accordingly, withdrawal of this rejection is respectfully requested.

C. Regarding enablement

All of the claims pending in the current response, except for claims 100, 101, and 127, are rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabling. Applicants respectfully traverse the rejection.

The Action takes the position that the specification does not provide sufficient guidance for claims requiring a mere 70% homology to SEQ ID NO:10.

As an initial matter, even under the Action's position, why are several of the other pending claims rejected? Specifically, claims 123 to 126 recite as follows:

123. A preparation comprising a heparanase protein, wherein said heparanase protein comprises amino acid residues 12 to 136 of SEQ ID NO: 10, and wherein said preparation is pure enough to elicit anti-heparanase antibodies.

124. The preparation of claim 123, wherein said heparanase protein has heparanase catalytic activity or is cleavable so as to acquire said heparanase catalytic activity.

125. A preparation comprising a heparanase protein, wherein said heparanase protein comprises amino acid residues 500 to 543 of SEQ ID NO: 10, and wherein said preparation is pure enough to elicit anti-heparanase antibodies.

126. The preparation of claim 125, wherein said heparanase protein has heparanase catalytic activity or is cleavable so as to acquire said heparanase catalytic activity.

Based on even the Action's own enablement position, Applicants respectfully submit that claims 123 to 126 are enabled and, therefore, request that this rejection regarding these claims be withdrawn.

Regarding the remaining claims under this rejection, Applicants have previously introduced the *Sun* case and made specific arguments as to why, under *Sun*, much broader enablement in this case must be found. In response, the Action takes the position that "the two applications [*Sun* and the subject application] are two different applications and that the determination of those factors considered to be relevant to whether undue experimentation is required is specific to each application."

What exactly is different about the *Sun* decision that merited the Board to reach such a vastly different finding than the one reached here? So far, the Action is completely silent on this point. And if the silence continues, it will impact Applicant's decision to appeal this issue. If appealed before the Board, one side will make specific arguments (as have already been made for the record) of how and why the facts of *Sun* compare favorably to the fact of this case and, therefore, compel a similar result. Will the other side simply restate, in conclusory fashion and without any further explanation, that the facts in the two cases are simply different?

The Action seems to take the position that anything greater than 95% homology with SEQ ID NO:10 encompasses more variants than can be routinely screened with a reasonable expectation of success. If this is true, why did the Board in *Sun* find that the variants encompassed by 80% homology to the WEE1 protein can be routinely screened with a reasonable expectation of success?

As discussed in the previous response, both the WEE1 protein in *Sun* and the heparanase protein here have routine assays for screening. And, as discussed in the previous response, the declaration previously submitted in this case shows **far more** detailed guidance in modifying the heparanase protein of the subject invention that the guidance cited by the Board in *Sun* regarding the WEE1 protein.

In summary, the Board's decision in *Sun* dictates a finding of enablement here. If the Examiner disagrees with this assessment, Applicants are entitled to know precisely why this is not the case.

Finally, Applicants respectfully remind the Examiner that in Sun a claim to 80% homology was found to be enabled. Similarly, pending claim 98 requires 80% homology, and pending claim 99 only 90% homology. Applicants would consider a compromise on this issue if the Examiner offers one.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

D. Regarding anticipation

All of the pending claims continue to be rejected under 35 U.S.C. § 102 as allegedly anticipated by Fuks et al. (U.S. Pat. No. 5,362,641; hereinafter "Fuks"). Applicants respectfully traverse the rejection, noting that many of the claims under this rejection have been canceled herein without prejudice.

As an initial matter, Applicants note that claim 127 is rejected under this allegation. However, claim 127 reads as follows:

127. The preparation of claim 97, wherein said heparanase protein comprises SEQ ID NO: 10, provided that said amino acid sequence has a phenylalanine residue instead of a tyrosine residue at position 246.

Claim 127 (as well as new claims 128 and 129) is directed to a variant that is not taught or made inherent by Fuks. Accordingly, withdrawal of this rejection with respect to these claims is requested.

Regarding the remaining claims, the Action takes the position that the preparation of Fuks "can elicit anti-heparanase antibodies" because it is somehow capable of being further purified to reach this level. As stated in the previous response, Applicants respectfully disagree with the Action's interpretation of this phrase.

Nevertheless, to promote prosecution of the subject application and to finally receive a long-sought allowance, Applicants have amended claims 97, 123 and 125 (and all claims dependent thereon) to require that the claimed preparation "be pure enough to elicit anti-heparanase antibodies."

Accordingly, Applicants respectfully request that this rejection be withdrawn.

III. CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,

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Registration Number 40,338

Date: August 9, 2006

Encl:
One month extension fee